

FORM PTO-1449
INFORMATION DISCLOSURE STATEMENT

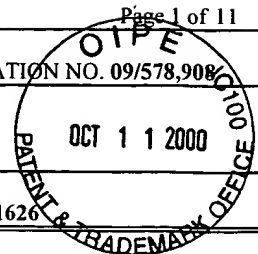
ATTY. DOCKET NO. 00166.0051-005

APPLICATION NO. 09/578,908

APPLICANT Mesens *et al.*

FILING DATE May 26, 2000

GROUP 1626



U.S. PATENT DOCUMENTS

| EXAMINER INITIALS | REF. NO. | DOCUMENT NUMBER | GRANT DATE | NAME | CLASS | SUB-CLASS | FILING DATE |
|-------------------|----------|-----------------|------------|-------------------------|-------|-----------|-------------|
| ES | AA1 | 3,197,180 | 07/1965 | Bates <i>et al.</i> | ET | T | |
| | AB1 | 3,523,906 | 08/1970 | Vrancken <i>et al.</i> | | | |
| | AC1 | 3,691,090 | 09/1972 | Kitajima <i>et al.</i> | | | |
| | AD1 | 3,737,337 | 06/1973 | Schnoring <i>et al.</i> | | | |
| | AE1 | 3,773,919 | 11/1973 | Boswell <i>et al.</i> | | | |
| | AF1 | 3,891,570 | 06/1975 | Fukushima <i>et al.</i> | | | |
| | AG1 | 3,923,288 | 12/1976 | King <i>et al.</i> | | | |
| | AH1 | 3,960,757 | 06/1976 | Morishita <i>et al.</i> | | | |
| | AI1 | 4,034,965 | 07/1977 | King <i>et al.</i> | | | |
| | AJ1 | 4,111,402 | 09/1978 | Barbini <i>et al.</i> | | | |
| ES | AK1 | 4,128,641 | 12/1978 | Itil <i>et al.</i> | T | T | |

FOREIGN PATENT DOCUMENTS

| EXAMINER INITIALS | REF. NO. | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB-CLASS | TRANSLATION |
|-------------------|----------|-----------------|---------|----------------|-------|-----------|---|
| ES | ALI | 1 212 730 | 11/1970 | United Kingdom | T | T | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | AM1 | 1 351 811 | 03/1974 | United Kingdom | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | AN1 | 2 015 360 | 09/1979 | United Kingdom | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | AO1 | 0 052 510 | 05/1982 | Europe | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| ES | AP1 | 0 071 454 | 02/1983 | Europe | T | T | <input type="checkbox"/> Yes <input type="checkbox"/> No |

| EXAMINER INITIALS | REF. NO. | OTHER (Including Author, Title, Date, Pertinent Pages, etc.) |
|-------------------|----------|---|
| ES | AS 1 | Abstract of WO 94/10982, Kino <i>et al.</i> , "Sustained-release Microspheres Requiring No Surgical Implant - Contains Hydrophobic Antipsychotic Encapsulated in Biodegradable Polymer, Allowing Prolonged Therapeutic Effect by Infrequent Administration". (1994) |
| ES | AT 1 | Baker, J.R., "Motionless Mixers Stir Up New Uses," <i>Chemical Engineering Progress</i> : 32-38 (June 1991). |

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M. A. B. G. G. G.

DATE CONSIDERED

10/22/01

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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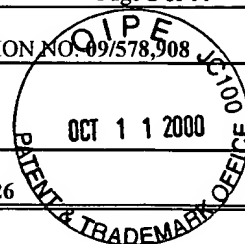
ATTY. DOCKET NO. 00166.0051-305

APPLICATION NO. 09/578,908

APPLICANT *Mesens et al.*

FILING DATE May 26, 2000

GROUP 1626



U.S. PATENT DOCUMENTS

| EXAMINER INITIALS | | DOCUMENT NUMBER | GRANT DATE | NAME | CLASS | SUB-CLASS | FILING DATE |
|-------------------|-----|-----------------|------------|--------------------------|-------|-----------|-------------|
| ES | AA2 | 4,201,482 | 05/1980 | Imhauser <i>et al.</i> | 1 | 1 | |
| | AB2 | 4,208,136 | 06/1980 | King <i>et al.</i> | 1 | 1 | |
| | AC2 | 4,329,331 | 05/1982 | Kallick <i>et al.</i> | 1 | 1 | |
| | AD2 | 4,335,127 | 06/1982 | Vandenberk <i>et al.</i> | 1 | 1 | |
| | AE2 | 4,337,261 | 06/1982 | Shutske <i>et al.</i> | 1 | 1 | |
| | AF2 | 4,324,870 | 08/1982 | Kennis <i>et al.</i> | 1 | 1 | |
| | AG2 | 4,352,811 | 10/1982 | Strupczewski | 1 | 1 | |
| | AH2 | 4,389,330 | 06/1983 | Tice <i>et al.</i> | 1 | 1 | |
| | AI2 | 4,443,451 | 04/1984 | Kennis <i>et al.</i> | 1 | 1 | |
| | AJ2 | 4,458,076 | 07/1984 | Strupczewski | 1 | 1 | |
| ES | AK2 | 4,485,107 | 11/1984 | Kennis <i>et al.</i> | 1 | 1 | |

FOREIGN PATENT DOCUMENTS

| EXAMINER INITIALS | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB-CLASS | TRANSLATION |
|-------------------|-----|-----------------|---------|----------------|-------|-----------|---|
| ES | AL2 | 2 120 113 | 11/1983 | United Kingdom | 1 | 1 | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | AM2 | 0 129 619 | 01/1985 | Europe | 1 | 1 | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | AN2 | 0 195 450 | 09/1986 | Europe | 1 | 1 | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | AO2 | 0 196 132 | 10/1986 | Europe | 1 | 1 | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| ES | AP2 | 0 248 531 | 12/1987 | Europe | 1 | 1 | <input type="checkbox"/> Yes <input type="checkbox"/> No |

| EXAMINER INITIALS | REF. NO. | OTHER (Including Author, Title, Date, Pertinent Pages, etc.) |
|-------------------|----------|--|
| ES | AR 2 | Borison, R.L. <i>et al.</i> , "Clinical Overview of Risperidone," in: Meltzer, H., Y., ed., <i>Novel Antipsychotic Drugs</i> , Raven Press, Ltd., N.Y.: 233-239 (1992) |
| ES | AS 2 | Chang, R. <i>et al.</i> , "Dissolution Characteristics of Polycaprolactone-Polylactide Microspheres of Chlorpromazine," <i>Drug Development and Industrial Pharmacy</i> , Vol. 12, No. 14, 2355-2380 (1986). |
| ES | AT 2 | Chemineer, "Kenics Static Mixers," <i>Bulletin</i> 800: 1-11 (1986). |

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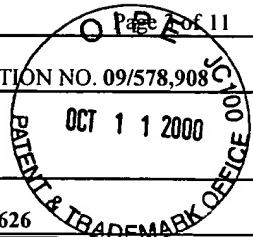
ATTY. DOCKET NO. 00166.0051-805

APPLICATION NO. 09/578,908

APPLICANT Mesens *et al.*

FILING DATE May 26, 2000

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U.S. PATENT DOCUMENTS

| EXAMINER INITIALS | | DOCUMENT NUMBER | GRANT DATE | NAME | CLASS | SUB-CLASS | FILING DATE |
|-------------------|-----|-----------------|------------|--------------------------|-------|-----------|-------------|
| ES | AA3 | 4,489,055 | 12/1984 | Couvreur <i>et al.</i> | | | |
| | AB3 | 4,511,258 | 04/1985 | Federighi <i>et al.</i> | | | |
| | AC3 | 4,529,727 | 07/1985 | Kennis <i>et al.</i> | | | |
| | AD3 | 4,530,840 | 07/1985 | Tice <i>et al.</i> | | | |
| | AE3 | 4,542,025 | 09/1985 | Tice <i>et al.</i> | | | |
| | AF3 | 4,585,482 | 04/1986 | Tice <i>et al.</i> | | | |
| | AG3 | 4,614,440 | 09/1986 | King <i>et al.</i> | | | |
| | AH3 | 4,616,937 | 10/1986 | King <i>et al.</i> | | | |
| | AI3 | 4,643,584 | 02/1987 | Allocca <i>et al.</i> | | | |
| | AJ3 | 4,665,075 | 03/1987 | Vandenberk <i>et al.</i> | | | |
| ES | AK3 | 4,675,189 | 06/1987 | Kent <i>et al.</i> | | | |

FOREIGN PATENT DOCUMENTS

| EXAMINER INITIALS | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB-CLASS | TRANSLATION |
|-------------------|-----|-----------------|---------|----------------|-------|-----------|---|
| ES | AL3 | WO 88/01165 | 02/1988 | PCT | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | AM3 | EP 0 266 119 | 05/1988 | 05/1988 Europe | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | AN3 | 0368 388 | 05/1990 | Europe | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | AO3 | WO 90/13361 | 11/1990 | WIPO | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| ES | AP3 | 91/13595 | 09/1991 | PCT | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |

| EXAMINER INITIALS | REF. NO. | OTHER (Including Author, Title, Date, Pertinent Pages, etc.) |
|-------------------|----------|--|
| ES | AR 3 | Chouinard, G. <i>et al.</i> , "A Canadian Multicenter Placebo-Controlled Study of Fixed Doses of Risperidone and Haloperidol in the Treatment of Chronic Schizophrenic Patients," <i>Journal of Clinical Psychopharmacology</i> , Vol. 13, No. 1, 25-40 (1993). |
| ES | AS 3 | Glazer, W.M. <i>et al.</i> , "Depot Neuroleptic Therapy: An Underutilized Treatment Option," <i>J. Clin. Psychiatry</i> 53 (12):426-433 (December, 1992). |
| ES | AT 3 | Heinrich, K. <i>et al.</i> , "Experimental Comparison of the Efficacy and Compatibility of Risperidone and Clozapine in Acute Schizophrenia," in: Kane, J.M. (ed), Risperidone: Major Progress in Antipsychotic Treatment. <i>Oxford Clinical Communications, Oxford</i> : 37-39 (1991). |

EXAMINER Chenabulay DATE CONSIDERED 10/27/01

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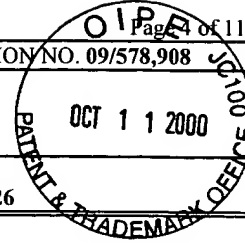
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APPLICANT Mesens *et al.*

FILING DATE May 26, 2000

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U.S. PATENT DOCUMENTS

| EXAMINER INITIALS | REF. NO. | DOCUMENT NUMBER | GRANT DATE | NAME | CLASS | SUB-CLASS | FILING DATE |
|-------------------|----------|-----------------|------------|------------------------|-------|-----------|-------------|
| ES | AA1 | 4,677,191 | 06/1987 | Tankana <i>et al.</i> | I | I | |
| | AB1 | 4,683,288 | 07/1987 | Tankana <i>et al.</i> | | | |
| | AC1 | 4,689,330 | 08/1987 | Janssen <i>et al.</i> | | | |
| | AD1 | 4,696,258 | 09/1987 | Magrath <i>et al.</i> | | | |
| | AE1 | 4,731,205 | 03/1988 | McNulty <i>et al.</i> | | | |
| | AF1 | 4,737,500 | 04/1988 | Sorg <i>et al.</i> | | | |
| | AG1 | 4,753,535 | 06/1988 | King <i>et al.</i> | | | |
| | AH1 | 4,765,204 | 06/1988 | Buchholz <i>et al.</i> | | | |
| | AI1 | 4,793,713 | 12/1988 | King <i>et al.</i> | | | |
| | AJ1 | 4,798,786 | 01/1989 | Tice <i>et al.</i> | | | |
| ES | AK1 | 4,804,663 | 02/1989 | Kennis <i>et al.</i> | I | I | |

FOREIGN PATENT DOCUMENTS

| EXAMINER INITIALS | REF. NO. | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB-CLASS | TRANSLATION |
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| ES | ALI | WO 91/17772 | 11/1991 | PCT | I | I | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | AM1 | 2 246 573 | 02/1992 | United Kingdom | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | ANI | 0 486 959 | 05/1992 | Europe | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | AO1 | WO 94/10982 | 07/1994 | WIPO | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| ES | API | WO 94/25460 | 11/1994 | WIPO | I | I | <input type="checkbox"/> Yes <input type="checkbox"/> No |

| EXAMINER INITIALS | REF. NO. | OTHER (Including Author, Title, Date, Pertinent Pages, etc.) |
|-------------------|----------|--|
| ES | AS 4 | Janssen and Niemegeers, "Chemistry and pharmacology of compounds related to 4-(4-hydroxy-4-phenyl-piperidino)-butyrophenone," <i>Arzneim.-Forsch. (Drug Res.)</i> 12:765-767 (1959). |
| ES | AT 4 | Janssen, P.A.J. <i>et al.</i> , "Is it Possible to Predict the Clinical Effects of Neuroleptic Drugs (Major Tranquilizers) from Animal Data?," <i>Arzneimitt. Forsch. (Drug Res.)</i> 10:1196-1206 (1965). |

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| EXAMINER | <i>Menschel</i> | DATE CONSIDERED | <i>Oct 27/01</i> |
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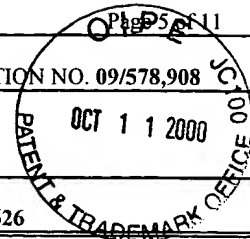
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| EXAMINER INITIALS | | DOCUMENT NUMBER | GRANT DATE | NAME | CLASS | SUB-CLASS | FILING DATE |
|-------------------|-----|-----------------|------------|-------------------------|-------|-----------|-------------|
| ES | AA2 | 4,808,007 | 02/1989 | King <i>et al.</i> | T | T | |
| | AB2 | 4,835,139 | 05/1989 | Tice <i>et al.</i> | | | |
| | AC2 | 4,883,666 | 11/1989 | Sabel <i>et al.</i> | | | |
| | AD2 | 4,897,268 | 01/1990 | Tice <i>et al.</i> | | | |
| | AE2 | 4,936,689 | 06/1990 | Federighi <i>et al.</i> | | | |
| | AF2 | 4,940,588 | 07/1990 | Sparks <i>et al.</i> | | | |
| | AG2 | 4,994,281 | 02/1991 | Muranishi <i>et al.</i> | | | |
| | AH2 | 5,008,114 | 04/1991 | Lovrecich | | | |
| | AI2 | 5,075,109 | 12/1991 | Tice <i>et al.</i> | | | |
| | AJ2 | 5,102,872 | 04/1992 | Singh <i>et al.</i> | | | |
| ES | AK2 | 5,158,952 | 10/1992 | Janssen <i>et al.</i> | T | T | |

FOREIGN PATENT DOCUMENTS

| EXAMINER INITIALS | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB-CLASS | TRANSLATION |
|-------------------|-----|-----------------|---------|---------|-------|-----------|---|
| ES | AL2 | WO 95/13799 | 05/1995 | WIPO | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | AM2 | | | | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | AN2 | | | | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | AO2 | | | | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | AP2 | | | | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |

| EXAMINER INITIALS | REF. NO. | OTHER (Including Author, Title, Date, Pertinent Pages, etc.) |
|-------------------|----------|--|
| ES | AR 5 | Janssen, P.A.J. <i>et al.</i> , "Pharmacology of Risperidone (R 64 766), a New Antipsychotic With Serotonin - S ₂ and Dopamine - D ₂ Antagonistic Properties," <i>The Journal of Pharmacology and Experimental Therapeutics</i> , Vol. 244, No. 2, 685-693 (1988). |
| ES | AS 5 | Koch Engineering Company Inc., "All Mixing Problems Are Not Alike," 1 page, <i>Product Brochure</i> . |
| ES | AT 5 | Koch Engineering Company Inc., "Static Mixing Technology," Article: 1-15 (1991). |

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DATE CONSIDERED

01/29/01

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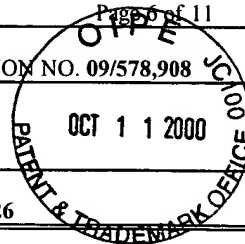
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OCT 11 2000

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U.S. PATENT DOCUMENTS

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|-------------------|-----|-----------------|------------|------------------------|----------|-----------|-------------|
| <i>E</i> | AA3 | 5,407,609 | 04/1995 | Tice <i>et al.</i> | <i>I</i> | <i>I</i> | |
| | AB3 | 5,453,425 | 09/1995 | Francois <i>et al.</i> | | | |
| | AC3 | 5,478,564 | 12/1995 | Wantier <i>et al.</i> | | | |
| | AD3 | 5,650,173 | 07/1997 | Ramstack <i>et al.</i> | | | |
| <i>E</i> | AE3 | 5,792,477 | 08/1998 | Rickey <i>et al.</i> | <i>I</i> | <i>I</i> | |
| | AF3 | | | | | | |
| | AG3 | | | | | | |
| | AH3 | | | | | | |
| | AI3 | | | | | | |
| | AJ3 | | | | | | |
| | AK3 | | | | | | |

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| | AL3 | | | | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
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| EXAMINER INITIALS | REF. NO. | OTHER (Including Author, Title, Date, Pertinent Pages, etc.) |
|-------------------|----------|--|
| <i>E</i> | AR 6 | Koflo Corporation, "Static In-Line Mixers," 4 pages, Product Brochure |
| <i>E</i> | AS 6 | Komax Systems, Inc., "Triple Action Static Mixers," 2 pages, Product Brochure |
| <i>E</i> | AT 6 | Leysen, J.E., <i>et al.</i> , "Biochemical Profile of Risperidone, a New Antipsychotic," <i>The Journal of Pharmacology and Experimental Therapeutics</i> , Vol. 247, No. 2, 661-670 (1988). |

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DATE CONSIDERED

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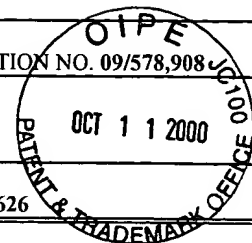
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| | AA1 | | | | | | |
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| | AN1 | | | | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
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| EXAMINER INITIALS | REF. NO. | OTHER (Including Author, Title, Date, Pertinent Pages, etc.) |
|-------------------|----------|--|
| E | AS 7 | Leyson, J.E. <i>et al.</i> , "In vitro receptor binding and neurotransmitter uptake inhibition profile of R 64 766, R 76 477, R 78 543 and 78 544," Janssen Research Foundation, Beerse, Belgium, M 79120, <i>Preclinical Research Report R 64 766/28</i> , 11 pages (January 1991). |
| E | AT 7 | Maulding, H.V. <i>et al.</i> , "Biodegradable Microcapsules: Acceleration of Polymeric Excipient Hydrolytic Rate By Incorporation of a Basic Medicament," <i>Journal of Controlled Release</i> , 3: 103-117 (1986). |

EXAMINER

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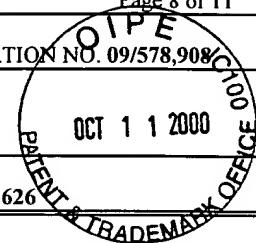
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| | AA2 | | | | | | |
| | AB2 | | | | | | |
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| | AF2 | | | | | | |
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| | AI2 | | | | | | |
| | AJ2 | | | | | | |
| | AK2 | | | | | | |

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| | AN2 | | | | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
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|-------------------|----------|---|
| | AR 8 | Megen, A.A.H.P. <i>et al.</i> , "Comparative Pharmacology of Risperidone, Its Major Metabolite R 76 477 ⁽⁺⁾ and the Corresponding Enantiomers R 78 543 ⁽⁺⁾ and R 78 544 ⁽⁺⁾ in Rats and Dogs," Janssen Research Foundation, Beerse, Belgium, N74694, <i>Preclinical Research Report</i> R 64 766/23 (June 1990). |
| | AS 8 | Megens, A.A.H.P. <i>et al.</i> , "In Vivo Pharmacological Profile of 9-Hydroxyrisperone, the Major Metabolite of the Novel Anti and Haloperidol," Janssen Research Foundation, Beerse, Belgium, N 96295, <i>Preclinical Research Report</i> R 64 766/R 76 477 (May 1993). |
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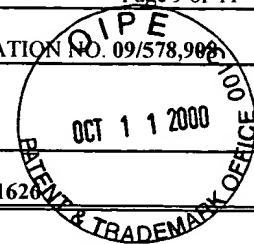
ATTY. DOCKET NO. 00166.0051-005

APPLICATION NO. 09/578,900

APPLICANT *Mesens et al.*

FILING DATE May 26, 2000

GROUP 1620



U.S. PATENT DOCUMENTS

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|-------------------|----------|--|
| <i>E</i> | AR 2 | Mutsakis <i>et al.</i> , Advances In Static Mixing Technology," <i>Chemical Engineering Progress</i> : 42-48 (July 1986). |
| <i>E</i> | AS 9 | Niemegeers and Janssen, "A Systemic Study of the Pharmacological Activities of Dopamine Antagonists," in: <i>Life Science</i> 24 (24):2201-2216, Pergamon Press Ltd. (1979). |
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Kenneth S. Adley

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APPLICATION NO. 09/578,908

APPLICANT Mesens *et al.*

FILING DATE May 26, 2000

GROUP 1626



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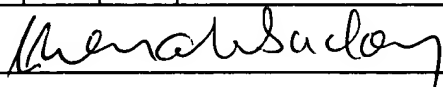
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|---|----------|---|
|  | AS 10 | Photocopy of an unofficial English Translation of Japanese Patent Application No. Hei-04 (1992)-332441, "Sustained-Release Microsphere and Process for Producing the Same," filed by Yoshitomi Pharmaceutical Industries, Ltd., which is the priority document of PCT Application No. 94/10982, pp. 1-12. |
|  | AT 10 | Ramtoola, Z., <i>et al.</i> , "Release Kinetics of Fluphenazine from Biodegradable Microspheres," <i>Journal of Microencapsulation</i> , Vol. 8, No. 4, 415-423 (1992). |

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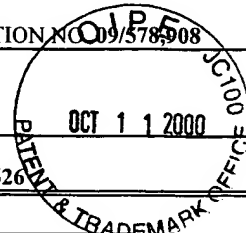
APPLICATION NO. 09/578,908

APPLICANT *Mesens et al.*

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| EXAMINER INITIALS | | DOCUMENT NUMBER | GRANT DATE | NAME | CLASS | SUB-CLASS | FILING DATE |
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| EXAMINER INITIALS | REF. NO. | OTHER (Including Author, Title, Date, Pertinent Pages, etc.) |
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| <i>ES</i> | AR 11 | Streiff, F., "In-Line Dispersion and Mass Transfer using Static Mixing Equipment," <i>Sulzer Technical Review</i> 3:108-114 (1977). |
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| | AT 11 | |

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